(4) On or after July 1, 1991, epoetin (EPO) for use at home by a home dialysis patient and, on or after January 1, 1994, by a dialysis patient, if it has been determined, in accordance with \$405.2163 of this chapter, that the patient is competent to use the drug safely and effectively.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 405.2137 of this chapter contains specific details.)

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 26959, May 25, 1994]

§410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

- (a) If the kidney is intended for an individual who has end-stage renal disease and is entitled to Medicare benefits; and
- (b) Regardless of whether the donor is entitled to Medicare.

§410.56 Screening pelvic examinations.

- (a) Conditions for screening pelvic examinations. Medicare Part B pays for a screening pelvic examination (including a clinical breast examination) if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a certified nurse midwife (as defined in section 1861(gg) of the Act), or a physician assistant, nurse practitioner, or clinic nurse specialist (as defined in section 1861(aa) of the Act) who is authorized under State law to perform the examination.
- (b) *Limits on coverage of screening pelvic examinations.* The following limitations apply to coverage of screening pelvic examination services:
- (1) General rule. Except as specified in paragraphs (b)(2) and (b)(3) of this section, payment may be made for a pelvic examination performed on an asymptomatic woman only if the individual

has not had a pelvic examination paid for by Medicare during the preceding 35 months following the month in which her last Medicare-covered screening pelvic examination was performed.

- (2) More frequent screening based on high-risk factors. Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 36 months if the test is performed by a physician or other practitioner specified in paragraph (a) of this section, and there is evidence that the woman is at high risk (on the basis of her medical history or other findings) of developing cervical cancer, or vaginal cancer, as determined in accordance with the following risk factors:
- (i) High risk factors for cervical cancer:
- (A) Early onset of sexual activity (under 16 years of age).
- (B) Multiple sexual partners (five or more in a lifetime).
- (C) History of a sexually transmitted disease (including HIV infection).
- (D) Absence of three negative or any Pap smears within the previous 7 years.
- (ii) High risk factor for vaginal cancer: DES (diethylstilbestrol)-exposed daughters of women who took DES during pregnancy.
- (3) More frequent screening for women of childbearing age. Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 36 months if the test is performed by a physician or other practitioner as specified in paragraph (a) of this section for a woman of childbearing age who has had such an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term "woman of childbearing age" means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner as specified in paragraph (a) of this section, to be of childbearing age, based on her medical history or other findings.
- (4) Limitation applicable to women at high risk and those of childbearing age.

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Payment is not made for a screening pelvic examination for women considered to be at high risk (under any of the criteria described in paragraph (b)(2) of this section), or who qualify for coverage under the childbearing provision (under the criteria described in paragraph (b)(3) of this section) more frequently than once every 11 months after the month that the last screening pelvic examination covered by Medicare was performed.

[62 FR 59101, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998]

§410.57 Pneumococcal vaccine and flu vaccine.

- (a) Medicare Part B pays for pneumococcal vaccine and its administration when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.
- (b) Medicare Part B pays for the influenza virus vaccine and its administration.

[63 FR 35066, June 26, 1998]

$\$\,410.58$ Additional services to HMO and CMP enrollees.

Services not usually covered under Medicare Part B may be covered as medical and other health services if they are furnished to an enrollee of an HMO or a CMP and the following conditions are met:

- (a) The services are—
- (1) Furnished by a physician assistant or nurse practitioner as defined in §491.2 of this chapter, or are incident to services furnished by such a practitioner; or
- (2) Furnished by a clinical psychologist as defined in §417.416 of this chapter to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, or are incident to those services.
- (b) The services are services that would be covered under Medicare Part B if they were furnished by a physician or as incident to a physician's professional services.

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) Basic rule. Medicare Part B pays for outpatient occupational therapy

services if they meet the following conditions:

- (1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine
- (2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.
 - (3) They are furnished-
- (i) By a provider as defined in §489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or
- (ii) By or under the personal supervision of an occupational therapist in private practice as described in paragraph (c) of this section.
- (b) Outpatient occupational therapy services furnished to certain inpatients of a hospital or a CAH or SNF. Medicare Part B pays for outpatient occupational therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.
- (c) Special provisions for services furnished by occupational therapists in private practice.
- (1) Basic qualifications. In order to qualify under Medicare as a supplier of outpatient occupational therapy services, each individual occupational therapist in private practice must meet the following requirements:
- (i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.
- (ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types:
 - (A) An unincorporated solo practice.
- (B) A partnership or unincorporated group practice.
- (C) An unincorporated solo practice, partnership, or group practice, a professional corporation or other incorporated occupational therapy practice. Private practice does not include any individual during the time he or she is working as an employee of a provider.